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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RADEMACHER, MARK A

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary	Application No. 09/596,730	Applicant(s) MARTIN ET AL.	
	Examiner Mark Rademacher	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on ____ is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 4, 5 and 31-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicants recite that the display adjusting circuit means has “coded control instructions” or “programmed control instructions”. The originally filed disclosure does not provide a description of the coded control instructions that conveys to one with ordinary skill that the applicant had possession of an apparatus including coded control instructions or programmed control instructions.

3. If the applicants contend that support for these limitations was given in the original disclosure, the applicant's are invited to specifically point to the support in the original disclosure.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-17, 19, 20 and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 5,246,995 to *Sullivan et al.*

6. *Sullivan et al* disclose all of the *structural* elements recited in the apparatus claims.

7. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959).

“[A]pparatus claims cover what a device *is*, not what a device *does*.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original). MPEP 2114.

8. Accordingly, the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *See, In re Hutchison*, 69 USPQ 138 (CCPA 1946). Accordingly, the applicant’s recitation of functions which the control unit, adjusting circuit, averagers and pressure sensor are “adapted to” (or like language) performed not entitled to any patentable weight.

9. *Sullivan et al* disclose a respiratory apparatus a blower (air blower 21), a patient interface (nose mask 12), a control unit having and adjusting circuit and a first averager (amplifier/filter/processor unit 26) and a display adapted to show the breathing signal. The display that *Sullivan et al* disclose takes the form of a record created by the processor/recorder of the breathing signals from the microphone. These processed signals are recorded as a time chart or a table that is reviewed by a physician. In fact and example of such a display is shown in FIG 2a. See column 6, lines 5-8 and column 8, line 61 through column 9, line 6.

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10. With respect to claim 2, *Sullivan et al* disclose a pressure sensor (snoring detection means 22 having pressure detection means and microphone 11; see column 9, lines 66-68 and column 14, lines 45-48).

11. With respect to claim 3, *Sullivan et al* disclose a baseline generator (filter amplifier/processor 26, which generates a control signal, among other functions; column 11, lines 58-61).

12. Claims 4-5 do not add additional structural limitations to the parent claims. Moreover, FIGS 7 and 8 and accompanying discussion describe the functionality recited in these claims.

13. Similarly, *Sullivan et al* disclose all of the structural limitations recited in claims 6-13.

14. The respiratory apparatus described by *Sullivan et al* includes a blower, a patient interface, a control unit coupled to either the patient interface or the blower and that includes a signal processing unit and adjusting circuit, and a display.

15. Claims 7-13 do not recite additional structural elements and are therefore also anticipated by the *Sullivan et al* disclosure. In addition, the *Sullivan et al* disclose the functional limitations therein. See FIGS 7 and 8 and the accompanying discussion.

16. *Sullivan et al* anticipate method claims 14-17, 19, 20, 24, 25 and 26-29 as well. *Sullivan et al* disclose a method for presenting a respiration signal including the steps of determining a parameter within the device related to the flow of pressurized air and the breathing of the patient, adjusting the parameter based on a baseline signal to generate a respiration signal within a predetermined range based on an average value of the respiration signal. See *Sullivan et al*, FIGS 7 and 8 and accompanying discussion.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 18, 21-23 and 30 rejected under 35 U.S.C. 103(a) as being unpatentable over *Sullivan et al*, and *Sullivan et al* in view of US patent no. 4,957,107 to *Sipin*.

19. *Sullivan et al* disclose a method including the steps of determining a parameter with the device related to the flow of pressurized air and the breathing of the patient, adjusting the signal based on a baseline signal to generate a respiration signal within a predetermined range based on the respiration signal and displaying the signal. *Sullivan et al* also disclose the steps of determining an absolute difference between said average value and the baseline signal and if the absolute difference is less than a first threshold then setting said baseline signal to the average value. See *Sullivan et al* FIGS 7 and 8, and the accompanying discussion.

20. *Sullivan et al* do not expressly disclose that the average value is calculated over a period of about 12 seconds, *Sullivan et al* do disclose that the average value is calculated over 4 and 64 inhales. See FIG 8.

21. *Sipin* discloses a gas delivery apparatus having the same general structure as that disclosed by *Sullivan et al*. The apparatus includes logic that calculates an average flow rate over time periods ranging from 0.3 seconds to 10 seconds. See Table 1, B(3) and (4), and D(3) and (8).

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22. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the *Sullivan et al* method and apparatus to take averages over time periods shorter than a typical breath of a person, and for the particular time periods specified in claims 18, 21-23 and 30.

23. One of ordinary skill in the art would have been motivated to make this modification in order to optimize the responsiveness of the method and apparatus disclosed by *Sullivan et al*.

24. Optimizing a variable in a system, such as the period over which an average is calculated, has been held to be obvious in light of prior art that disclose the general working range of the variable.

25. For example, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235

(CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%).

See also In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). *See also, Merck & Co. Inc. v. Biocraft*

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Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Claims 31-34

26. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 5245995 to *Sullivan et al.*

27. *Sullivan et al* disclose all of the features recited in claims 31 and 34. See, FIGS 7 and 8 and accompanying discussion except for a display screen. Instead Sullivan et al disclose that the respiration signal is displayed on a chart recorder.

28. The use of display screens to display respiratory signals was well known at the time of invention. See, e.g., US patent no. 6158432 to *Biondi et al.* In fact, the applicants indicate that chart recorders and display screens are equivalent display means in the specification. See page 5, lines 21-23 of the applicants' specification.

29. At the time of invention, it would have been obvious to one with ordinary skill in the art to substitute a display screen for the chart recorder disclosed by *Sullivan et al.* One would have been motivated to do so in order to eliminate for chart paper.

Response to Arguments

30. The objections to the drawings, claims and specification raised in the initial Office Action mailed on January 15, 2003 are withdrawn. The proposed amendments to the drawings are acceptable. The rejections raised under 35 U.S.C. 112 are also withdrawn.

31. Applicant's arguments filed May 12, 2003 have been fully considered but they are not persuasive.

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32. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph if it meets the following 3-prong analysis: (A) the claim limitations must use the phrase “means for ” or “step for ”; (B) the “means for ” or “step for ” must be modified by functional language; and (C) the phrase “means for ” or “step for ” must not be modified by sufficient structure, material or acts for achieving the specified function. MPEP 2181.

33. With respect to the first prong of this analysis, a claim element that does not include the phrase “means for” or “step for” will not be considered to invoke 35 U.S.C. 112, sixth paragraph.

34. If an applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant must either: (A) amend the claim to include the phrase “means for” or “step for” in accordance with these guidelines; or (B) show that even though the phrase “means for” or “step for” is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112 , sixth paragraph. MPEP 2181.

35. Because the applicants have not amended the claim to recite “means for” (applicants have instead have recited “display adjustment circuit means adapted to”) and because the applicants have not shown how the limitation does not set forth sufficient structure that would preclude the application of 35 U.S.C. 112, sixth paragraph. Accordingly, it is the examiners position that contrary to the applicants’ remarks the claims as amended do not invoke 35 U.S.C. sixth paragraph.

36. It is the examiner’s position that the apparatus disclosed by *Sullivan et al* includes all of the structures recited in the claims and that the structures are fully capable of performing the intended function recited in the claims.

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37. Moreover, even if the intended function of the claimed apparatus were to be given patentable weight, the apparatus disclosed by *Sullivan et al* performs the function of restricting the breathing signal within a predetermined display range because in controlling the respiration of the patient according to the long term and short term averages of the respiration signal, the displayed respiration signal itself is inherently restricted within a predetermined display range. The predetermined display range being the predetermined range of normal, non-apnea breathing. Similarly, *Sullivan et al* (or *Sullivan et al* and *Sipin*) teach the method claims recited.

38. With respect to the "coded control instructions" recited in claims 4 and 5, it is the examiner's position that the apparatus disclosed by *Sullivan et al* must include such instructions to perform the functions disclosed.

Final Action

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

39. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR

July 22, 2003


GLENN K. DAWSON
PRIMARY EXAMINER